UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,567	04/16/2004	Ryszard M. Lec	DXU-0007	2115

23377 7590 10/16/2007

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,567	LEC ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-51* is/are pending in the application.

4a) Of the above claim(s) *17-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/27/07, 4/26/06, 2/23/06, 1/24/05, 11/22/04.

DETAILED ACTION

Election/Restrictions

1. Claims 1-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 21 August 2007.

2. Applicant's election of claims 33-51 in the reply filed on 21 August 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

3. Claims 41 and 47 objected to because of the following informalities:

In claim 41, it is not clear whether the transducer itself is extended into the blood by the claimed distances, or whether an effect generated by the transducer applies to the blood only by these distances; for examination purposes, it will be treated as the distance the transducer's effect travels.

In claim 47, it is not clear how the higher and lower frequencies are related to the claimed invention – for clarity, it is suggested that this be amended to include a phrase similar to --wherein the varying signal applied by the transducer is a frequency value-- after "collagen".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses the phrase "biological sensing media", but this term is not defined in the specification or claims of the present application; additionally, the term is not even *present* in the specification or original set of claims. It appears that applicant is attempting to identify the component labeled as "bio-sensing element" in figure 1; for examination purposes, the claims will be treated as such.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 33-35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Grzegorzewski (US Patent 5494639).

Regarding claim 33, Grzegorzewski discloses a blood analysis device comprising a transducer element (element 8), biological sensing media in communication with the transducer (element 13), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (element 51), an inlet port to direct blood to the transducer element (element 11), and a signal processor in communication with the transducer that determines a blood characteristic from the blood's response to the applied signal (element 52).

Regarding claim 34, Grzegorzewski discloses the transducer as a piezoelectric element (column 4, line 25).

Regarding claim 35, Grzegorzewki further discloses the transducer including a plurality of sensors (electrodes 14).

Regarding claim 37, Grzegorzewski discloses varying an applied frequency (column 3, lines 43-53; column 6, lines 8-10).

7. Claims 33, 35, and 47-50 are rejected under 35 U.S.C. 102(B) as being anticipated by Jina (US Patent 6673622).

Regarding claim 33, Jina discloses a blood analysis device comprising a transducer element (elements 22), biological sensing media (column 9 line 64 to column 10 line 13), an inlet port (element 14), and a signal driver for applying a variable signal to the transducer and a signal processor for analyzing the blood's response to the varying signal to determine a characteristic (column 6, lines 30-67).

Regarding claim 35, Jina discloses the transducer comprising a plurality of sensing elements (figures 2-6).

Regarding claim 47, Jina further discloses a bulk bioactive material to facilitate blood characteristic determination (column 7 line 53 to column 8 line 14).

Regarding claims 48-50, Jina further discloses data storage, processing, and transmission, including storing blood data and providing information to a patient via a display (column 6 line 30 to column 7 line 23).

8. Claims 33 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawakami (US Patent 5728583).

Regarding claim 33, Kawakami discloses a blood analysis device comprising a transducer (elements 50), biological sensing media (element 84), an inlet (element 22, 23, 61, and 62), a signal driver for driving and varying a transducer value and a signal processor for measuring the blood's response to the varying value and determining a blood characteristic (column 3, lines 22-25; column 4, lines 39-43).

Regarding claims 37-40, Kawakami discloses the transducer signal being a resonant frequency ranging between 1 kHz and 10 GHz (column 6, lines 24-25).

9. Claims 33 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Freiherr Von Der Goltz (US Patent 7223365).

Regarding claim 33, Freiherr Von Der Goltz discloses a blood analysis device comprising a transducer element (column 3, lines 2-17; element 4), biological sensing media in communication with the transducer (column 2, lines 49-53), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (element 17, 18), an inlet port for delivering blood to the transducer element (element 5), and a signal processor in connection with the transducer for determining a blood characteristic from the blood's response to the varying signal (elements 9, 18).

Regarding claim 42, Freiherr Von Der Goltz further discloses a catheter (element 57).

10. Claims 33 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoonen (US Patent 5174291).

Regarding claim 33, Schoonen discloses a blood analysis device comprising a transducer element (elements 13, 15), biological sensing media in communication with the transducer (column 5, lines 21-27; column 9, lines 25-30), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (element 12), an inlet port for delivering blood to the transducer element (element 4),

and a signal processor in connection with the transducer for determining a blood characteristic from the blood's response to the varying signal (column 10, lines 53-60).

Regarding claim 43, Schoonen further discloses the device being self-administered, since it may be worn by the patient (column 1, lines 19-20).

11. Claims 33, 48, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Stiene (US Patent Application Publication 2004/0072357).

Regarding claim 33, Stiene discloses a blood analysis device comprising a transducer element (elements 104), biological sensing media in communication with the transducer (paragraphs [0037]), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (paragraphs [0102], [0111], [0114]), an inlet port for delivering blood to the transducer element (element 102), and a signal processor in connection with the transducer for determining a blood characteristic from the blood's response to the varying signal (paragraphs [0044], [0052], [0053]).

Regarding claims 48 and 51, Stiene further discloses data processing, storage, and transmission, including wired and wireless communication between the device, a patient, and a health center (paragraphs [0044], [0055]-[0066], [0078], [0115]).

12. Claims 33 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Sohrab (US Patent Application Publication 2003/0212347).

Regarding claims 33 and 36, Sohrab discloses a blood analysis device comprising a bioactive transducer element (paragraphs [0041], [0047]), a biological

sensing media in communication with the transducer (paragraphs [0048]-[0049]), a signal driver in communication with the transducer that applies a signal to the transducer and can vary the value of that signal (paragraph [0049]), an inlet port to deliver blood to the transducer element (paragraphs {0010], [0045]-[0046]), and a signal processor in connection with the transducer to determine a blood characteristic from the blood's response to the signal (paragraph [0059]).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jina. The Examiner notes that Jina does not expressly disclose the effect generated by the transducer traveling between 1 nm and 1 cm into the blood from the transducer's surface. However, the distance the signal travels is a function of the sample volume, as well as the type of signal being applied and the strength and frequency of that signal. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the device such that the transducer's effect would travel between 1 nm and 1 cm from its surface.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2002/0169394 to Eppstein, which discloses similar inventions.

US Patent Application Publication 2006/0079740 to Silver, which discloses similar inventions.

US Patent 5447440 to Davis, which discloses similar inventions.

US Patent 4026671 to Simons, which discloses similar inventions.

US Patent 6709390 to Marie Pop, which discloses similar inventions.

US Patent Application Publication 2004/0249292 to Davis, which discloses similar inventions.

US Patent Application Publication 6046051 to Jina, which discloses similar inventions.

US Patent 5564419 to Lundsgaard, which discloses similar inventions.

US Patent 6338821 to Jina, which discloses similar inventions.

US Patent Application Publication 2005/0233466 to Wright, which discloses similar inventions.

US Patent 5421328 to Bedingham, which discloses similar inventions.

US Patent Application Publication 2005/0148899 to Walker, which discloses similar inventions.

US Patent 5110727 to Oberhardt, which discloses similar inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ket

CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700